REMARKS

This is a full and timely response to the Office Action mailed July 24, 2009, submitted concurrently with a third month extension of time to extend the due date for response to January 25, 2009.

By this Amendment, claim 11 has been amended to more particularly define the present invention. Further, new claims 23 and 24 have been added to further protect specific embodiments of the present invention. Thus, claims 11-24 are currently pending in this application with claim 19 being withdrawn. Support for the claim amendments and new claims can be readily found variously throughout the specification and the original claims, see, in particular, page 8, lines 4-13, page 22, line 11, page 23, lines 5-8, page 31, lines 3-9, and page 40, line 11, of the specification.

In view of these amendments, Applicant believes that all pending claims are in condition for allowance. Reexamination and reconsideration in light of the above amendments and the following remarks is respectfully requested.

Rejections under 35 U.S.C. §102 and §103

Claims 11-18 and 20-21 are rejected under 35 U.S.C. §102(b) as allegedly being anticipated by Chatterjee et al. (U.S. Patent Application Publication No. 2002/0168706). Further, claims 11 and 20-22 are rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Chatterjee et al. (U.S. Patent Application Publication No. 2002/0168706) in view of Reiter et al. (U.S. Patent No. 6,475,725). Applicant respectfully traverses these rejections.

To establish an obviousness rejection under 35 U.S.C. §103(a), four factual inquiries must be examined. The four factual inquiries include (a) determining the scope and contents of the prior art; (b) ascertaining the differences between the prior art and the claims in issue; (c) resolving the level of ordinary skill in the pertinent art; and (d) evaluating evidence of secondary consideration. *Graham v. John Deere*, 383 U.S. I, 17-18 (1966). In view of these four factors, the analysis supporting a rejection under 35 U.S.C. 103(a) should be made explicit, and should "identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the [prior art] elements" in the manner claimed. *KSR Int'l. Co. v. Telefex, Inc.*, 127 S. Ct. 1727, 82 USPQ2d 1385, 1396 (2007). Further, the Federal Circuit has stated that "rejections on obviousness

cannot be sustained with mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *In re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006). Finally, even if the prior art may be combined, there must be a reasonable expectation of success, and the reference or references, when combined, must disclose or suggest all of the claim limitations. *See in re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

Applicant submits that Chatterjee et al. either alone or in combination with Reiter et al. fails to teach or suggest the present invention of claims 11-18 and 20-22.

Chatterjee et al. is directed to in vitro production of protein from input mRNA or from input DNA that is transcribed efficiently to produce protein in improved quantities, and in vitro production of nucleic acid molecules (see paragraph [0003] of Chatterjee et al.). Chatterjee et al. further discloses that RNA or other nucleic acid molecules may be produced by mixing one or more nucleic acid templates and at least one component of the invention, such as inhibitors, energy sources, or cell extracts. The mixture is incubated under conditions sufficient to produce one or more peptides or proteins encoded by all or a portion of the template (see paragraph [0043] of Chatterjee et al.).

The extract of Chatterjee et al. is a cell lysate or exudate (see paragraph [0078] of Chatterjee et al.). The extract is processed to remove cellular debris through centrifugation, filtration, or chromatography (see paragraph [0079] of Chatterjee et al.). Both prokaryotic cells and eukaryotic cells can be used for the protein and/or nucleic acid synthesis (see paragraph [0078] of Chatterjee et al.). Further, Example 4 of Chatterjee et al., which relates to the purification of GamS, discloses a harvested cell pellet being frozen, thawed, resuspended in extract buffer, sonicated, and centrifuged (see paragraphs [0121]-[0122] of Chatterjee et al.).

In contrast to the present invention, Chatterjee et al. does not expressly disclose *rapid freezing* of the cell-cultured mammalian cell. In the present invention, a cultured mammalian cell is frozen in not longer than 10 seconds, and preferably, in not longer than 2 seconds. As a result, the components essential for protein synthesis may be inactivated without damage, contamination with RNase and the like can be prevented, and incorporation of a substance inhibiting translation reaction

can be avoided (see paragraphs [0030]-[0031] of the present Patent Application Publication No. 2006/0141559).

Rapid-freezing can be accomplished using an inert gas such as liquid nitrogen, liquid helium, and the like (see paragraph [0033] of the present Patent Application Publication). Although Example 4 of Chatterjee et al. broadly discloses freezing followed by thawing and centrifugation, Chatterjee et al. does not provide any specifics with regard to the freezing step. As such, the Examiner has no basis for asserting that Chatterjee et al. teaches *rapid freezing*.

Further, although some of Chatterjee et al.'s disclosure teaches aspects of cell-free protein synthesis, Example 4 of Chatterjee et al., in which GamS is purified, does not relate to a process of obtaining a *cell-free* extract. Example 4 of Chatterjee et al. only shows the step of purifying GamS protein, which is an additive of the reaction solution, *not* the step of preparing cell extract. In Chatterjee et al., the extract of *E. coli* is used, but the concrete preparation method of the extract is not disclosed or taught in paragraph [0078] or [0079], or even in the Examples of Chatterjee et al. Thus, Applicant submits that the freezing step in Chatterjee et al. is not employed in the same manner as the rapid-freezing step of the present invention.

Still further, the Examiner asserts that the recitation of "*a cultured mammalian cell extract liquid*" is a product-by-process limitation and therefore, the claimed method does not necessarily require all the steps of the preparation method (see page 3 of the Office Action). Although Applicant disagrees with the Examiner's position, Applicant has amended claim 11 to positively recite the cell extract liquid preparation step in claim 11. Further, claim 11 has been amended to more particularly define the rapidly freezing step as freezing the cultured mammalian cell in 10 seconds or less.

Applicant believes that such claim amendments address the Examiner's product-by-process concerns, and also help distinguish the rapid freezing step of the present invention from that which is disclosed by Chatterjee et al. As discussed above, Chatterjee et al. only discloses freezing broadly, and does not disclose freezing the cultured mammalian cell in 10 seconds or less. Therefore, it is clear that Chatterjee et al. fails to teach the newly added limitation.

The Examiner cites Reiter et al. to demonstrate that CHO K1-SFM cells and their use in the expression of recombinant proteins were known in the art at the time the present invention was

made (see page 7 of the Office Action). However, Reiter et al. fails to cure the deficiencies of Chatterjee et al. discussed above.

Thus, for these reasons, withdrawal of the present rejection is respectfully requested.